United States Court of Appeals for the Federal Circuit

01-1110

TRANSONIC SYSTEMS, INC.,

Plaintiff-Appellee,

v.

NON-INVASIVE MEDICAL TECHNOLOGIES CORPORATION
(doing business as In-Line Diagnostics Corporation),

Defendant-Appellant.

DECIDED: May 29, 2001

Before LOURIE, SCHALL, and LINN, Circuit Judges.

SCHALL, Circuit Judge.

DECISION

Non-Invasive Medical Technologies Corporation ("NMT") appeals from the order of the United States District Court for the District of Utah that granted the motion of Transonic Systems, Inc. ("Transonic") for a preliminary injunction related to NMT's alleged infringement of Transonic's

U.S. Patent No. 5,685,989 (the " '989 patent"). Transonic Sys., Inc. v. Non-Invasive Med. Tech. Corp., No. 1:99CV00041B (D. Utah Nov. 8, 2000) ("Transonic II"). Because we conclude that the district court erred in one respect in its claim construction, we vacate the preliminary injunction and remand the case for further proceedings consistent with this opinion.

DISCUSSION

I.

The '989 patent is directed to a method and apparatus for measuring blood flow in hemodialysis shunts, which are used, for example, in dialysis patients. '989 pat., col. 1, ll. 7-10. To measure shunt blood flow in accordance with the patent, the arterial and venous lines of the dialysis equipment are reversed from the normal dialysis configuration. Id. at col. 4, ll. 9-10. An arterial inlet, which removes blood from the patient's vascular system and takes it into the dialysis circuit, is located in the shunt downstream of a venous outlet, which returns blood to the patient's vascular system from the dialysis circuit. Id. at col. 4, ll. 10-13. The following steps are performed to determine shunt blood flow: Blood is removed from the patient's vascular system via the downstream outlet and taken into the dialysis circuit. Id. In the dialysis circuit, a physical parameter of the blood is changed to produce a distinguishable blood characteristic, and the changed blood is returned to the patient's vascular system via the upstream inlet. Id. at col. 4, ll. 13-27. Blood is again removed from the patient's vascular system via the downstream outlet and taken into the dialysis circuit. Id. A detector located somewhere along the dialysis circuit measures the distinguishable blood characteristic in the removed blood. Id. at 16-27. The measured amount of distinguishable blood characteristic is used to calculate shunt blood flow. Id. at 23-27.

Independent claims 1 and 9, set forth below, are the only claims at issue on appeal. The disputed claim terms are underlined:

> 1. A process for determining in an arterio-venous shunt blood flow in a cardiovascular circuit, comprising:
>
> delivering blood from a circulating system outside the cardiovascular circuit into an upstream location in an arterio-venous shunt connected in the cardiovascular circuit and carrying a shunt blood flow;
>
> mixing said delivered blood with said shunt blood flow;
>
> removing a portion of the mixed blood from said arterio-venous shunt at a location in the shunt which is downstream from said upstream location and delivering the removed portion of mixed blood to the circulating system;
>
> changing a selected blood parameter in blood flowing in said circulating system to produce a distinguishable blood characteristic in blood which is delivered to the arterio-venous shunt;
>
> measuring the amount of distinguishable blood characteristic in said removed portion of mixed blood; and

> calculating the rate of flow of said shunt blood flow in said arterio-venous shunt from said measured amount of distinguishable blood characteristic.

Id. at col. 8, ll. 34-55.

> 9. A process for determining patient blood flow in a patient hemodialysis shunt, comprising:
>
> removing blood from a downstream location in a hemodialysis shunt by way of an inlet connected to an inlet side of a hemodialysis circulating line to provide blood flowing in said circulating line;
>
> delivering the blood flowing in said circulating line by way of an outlet connected to an outlet side of said circulating line to an upstream location of said shunt, the blood from said outlet being delivered to said shunt so as to mix with patient blood flow in said shunt to produce mixed blood, whereby blood removed from said shunt by way of said inlet is a portion of said mixed blood;
>
> changing a selected blood parameter in said circulating line to produce a distinguishable blood characteristic at the outlet side of said circulating line;
>
> measuring in said circulating line the amount of said changed parameter present in said portion of the mixed blood; and
>
> determining the rate of patient blood flow in said shunt from the measured amount of said changed parameter.

Id. at col.9, ll.13-35.

II.

The district court conducted a Markman hearing and construed the claims in an opinion and order issued December 13, 1999. Transonic Sys., Inc. v. Non-Invasive Med. Tech. Corp., No. 1:99-CV-41 (D. Utah Dec. 13, 1999) ("Transonic I").

The court construed "mixing" in accordance with a dictionary definition proposed by Transonic: "the combining or putting together of two or more substances or things so that the constituents of each are diffused among those of the other(s)." Id., slip op. at 4-5. In so doing, the court rejected NMT's argument that Transonic's statement during prosecution that "complete mixing" was a primary feature of the invention limited the claim terms. Id. at 5. The court determined that, when read in context, the "isolated reference to 'complete mixing' appears to be a careless misstatement," and that "[n]othing in the prosecution history suggests [that Transonic] . . . intended to impart a limited meaning to the generic term 'mixing.'" Id. The court clarified its definition of "mixing" in its order granting Transonic's motion for a preliminary injunction: "Returning blood to the shunt will result in its mixing with the blood already flowing through the shunt much like the way water in two merging rivers naturally mixes together. That

is exactly the type of mixing this Court sought to adopt as the definition of the term 'mixing.'" Transonic II, slip op. at 7.

The dispute over the "changing a selected blood parameter" limitations centered on the manner in which the change is effected. The court determined that "changing" is an ordinary term and adopted a dictionary definition: "make different, modify or alter." Transonic I, slip op. at 6. The court rejected NMT's argument that "changing," as used in the claims, requires the addition of an indicator to the blood, determining that "nothing in the intrinsic evidence suggests that [Transonic] or [the Patent Office] effectively re-defined the term 'changing' for the purposes of the '989 patent.'" Id. at 6. The court found that the portions of the specification and the statements in the prosecution history cited by NMT merely described the preferred embodiment of the invention, and did not limit the scope of the claims. Id. at 6-7.

The parties agreed that the term "calculating," used in claim 1, and the term "determining," used in claim 9, should be accorded the same meaning, but disagreed as to what that meaning should be. Transonic argued that the terms mean determining "the actual blood flow using the measured amount of distinguishable blood characteristic," determining "a number related to the flow rate from which the flow rate can be determined," or "determining whether the flow rate is above or below a predetermined threshold." Id. at 7. In contrast, NMT argued that statements made during prosecution of the '989 patent required that the terms be limited to "determining a number representing the amount of flow of blood in the line per unit time without using a recirculation calculation, and using the equations set forth in the specification." Id. at 8.

The court rejected NMT's arguments. With regard to recirculation, the court determined that the prosecution statements cited by NMT were made to distinguish the determination of shunt recirculation from the determination of shunt flow rate, and did not indicate that methods that use information relating to recirculation rate to determine shunt blood flow are excluded from the claims. Id. at 8-9. With regard to the equations set forth in the specification of the '989 patent, the district court determined that the passages relied on by NMT were "taken out of context and puffed up to support [NMT's] position." Id. at 9. The court found that the equations "illustrate preferred embodiments," and determined that "no statements in the prosecution history suggest that [Transonic] or [the Patent Office] intended to limit the blood flow calculation to the preferred embodiment equations." Id.

The court also rejected Transonic's proposed definitions for "calculating" and "determining," finding that "nothing in the record . . . suggests that the terms . . . mean anything other than 'to determine by mathematical equation.'" Id. at 8. The court therefore construed the claim terms according to that broad dictionary definition. Id.

To rule on Transonic's motion for a preliminary injunction, the district court considered whether Transonic had established a likelihood of success of prevailing on the merits of its claim that NMT infringes the '989 patent. The court applied claims 1 and 9 of the '989 patent, as construed in Transonic I, to the accused method, NMT's Delta H method. Transonic II, slip op. at 3. The characteristics of the Delta H method were determined from an instruction manual provided with one of NMT's dialysis monitors. Id. at 6. The district court described the Delta H method as follows:

> [T]he Delta H method requires the user to reverse the dialyzer line configuration such that the input line is upstream in the shunt and the out-take line is

> downstream. The blood is taken from the patient and the percentage of red blood cells, or the level of hematocrit, is changed. The changed blood is returned to the shunt upstream and again removed downstream where the hematocrit level is measured to determine flow rate through the shunt.

Id. The court determined that this method met the limitations of the '989 patent claims. With regard to the disputed limitations, the court determined that "returning blood to the shunt will result in . . . mixing," as the court had construed that term. Id. at 7. With regard to "changing a selected blood parameter," the court found that "the percentage of red blood cells in the blood is clearly a physical characteristic of blood." Id. The court determined that "[i]t is impossible to logically conclude that changing the hematocrit level in the blood, returning the changed blood to the flow of the shunt, and measuring the downstream mixed blood hematocrit level is different from what is claimed in the mixing, changing, and measuring elements of claim 1 of the '989 patent." Id. The court therefore concluded that Transonic had established a likelihood of success of prevailing on the issue of infringement. Id. at 9.

The court also determined that Transonic had established a likelihood of success of prevailing on the issue of the validity of the '989 patent, id., and that Transonic was entitled to a presumption of irreparable harm because it had made strong showings of likelihood of success on the issues of infringement and validity. Id. at 9-10. The court found that the balance of hardships weighed in Transonic's favor, and that the public interest did not weigh in favor of either granting or denying the preliminary injunction. Id. at 10-11. The court therefore granted Transonic's motion for a preliminary injunction. Our jurisdiction over NMT's appeal of the preliminary injunction is based on 28 U.S.C. § 1292(c)(1).

III.

NMT's appeal of the district court's grant of Transonic's motion for a preliminary injunction is based on the court's claim construction. Claim construction is a question of law that we review de novo. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456, 46 USPQ2d 1169, 1174 (Fed. Cir. 1998) (en banc). NMT argues that the court misconstrued the "mixing," "changing," and "calculating" and "determining" limitations of the asserted claims.

With regard to the "mixing" limitations, NMT raises the same arguments that it raised before the district court, asserting that the statement in the prosecution history regarding "complete mixing" limits the scope of the claims. NMT also cites external evidence, including correspondence between the inventors and their patent attorney and articles authored by the inventors, as demonstrating that "complete mixing" is a required aspect of the invention. Finally, NMT argues that the district court's construction of "mixing" renders the term meaningless because mixing will always occur as a result of the "delivering" steps.

NMT argues that the "changing" limitations are drafted in step-plus-function form and, therefore, must be construed in accordance with 35 U.S.C. § 112, ¶ 6. When so construed, NMT argues, "changing" requires the addition of an indicator because that is the only corresponding act disclosed in the specification. NMT argues that even if the "changing" limitations are not construed under § 112, ¶ 6, statements in the prosecution history made by the applicant and by the examiner limit the "changing" step to the addition of an indicator. NMT also argues that the district court erred when it determined that the "blood parameter" that is

changed to produce a "distinguishable blood characteristic" includes chemical and biological characteristics of the blood, in addition to the physical characteristics disclosed in the specification.

After careful consideration, we reject NMT's arguments. We discern no error in the district court's construction of the "mixing and "changing" limitations or in its findings that those limitations are met by NMT's Delta H method. However, as far as the "calculating" and "determining" limitations are concerned, we believe that the district court's construction was too broad.

In construing patent claims, we look to the intrinsic evidence of record—the claims, the specification, and, if in evidence, the prosecution history. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582, 39 USPQ2d 1573, 1576 (Fed. Cir. 1996). "One purpose for examining the specification is to determine if the patentee has limited the scope of the claims." Watts v. XL Sys., Inc., 232 F.3d 877, 882, 56 USPQ2d 1836, 1839 (Fed. Cir. 2000). The '989 patent describes the determination of shunt blood flow with reference to specific equations. See, e.g., '989 pat., col. 1, ll. 56-61 ("Blood flow, Q, measured by the dilution method . . . is given by Q=V/S (Eq. 1)."); see also id. at col. 2, ll. 31, 34, 57, 67 (setting forth alternative equations 2-5); id. at col. 3, ll. 2, 24, 33 (setting forth alternative equations 6-8). Moreover, the "SUMMARY OF THE INVENTION" section of the patent teaches that "the blood flow relationships are calculated in accordance with the foregoing equations." Id. at col. 4, ll. 26-27. There is no description of "calculating" or "determining" blood flow that does not require the use of at least one of the disclosed equations. Moreover, no language in the specification indicates that the invention encompasses other methods of "calculating" or "determining" blood flow.

The prosecution history also may be "of critical significance in determining the meaning of the claims." Vitronics, 90 F.3d at 1582, 39 USPQ2d at 1577. During prosecution of the '989 patent, in response to an Office Action rejecting the pending claims, Transonic identified several "primary features of the invention." Included in these features is "[t]he calculation of shunt blood flow (line blood flow) from the sample via dilution principles as is taught in the present application." As discussed above, the only "calculation . . . via dilution principles" taught in the specification of the '989 patent revolves around the disclosed equations. In the same response, Transonic argued that the disclosed equations are critical to achieving the purpose of the invention and are novel over the prior art:

> The purpose of the invention is to measure shunt (blood line) blood flow, and for this purpose the application sets out the flow relationships which permit calculation of the line blood flow from other measurements. These relationships are not taught in the prior art . . . .

Moreover, Transonic distinguished a prior art reference by explaining that, "in the present invention[,] shunt flow is calculated from a dialysis flow and a concentration curve measurement." Taken together, these statements indicate that the disclosed equations are part of the claimed invention, play an important role in achieving the objects of the invention, and help to distinguish the invention from the prior art. By describing the invention in these terms, Transonic disclaimed any interpretations of the terms "calculating" and "determining" that do not reflect the stated significance of the disclosed equations to the invention as a whole. See Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576, 34 USPQ2d 1673,

1676 (Fed. Cir. 1995) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.").

The intrinsic evidence of the '989 patent—the claim language, the specification and the prosecution history—leads us to conclude that the claim terms "calculating" and "determining" must be construed as requiring the use of at least one of the equations set forth in the specification of the '989 patent. Because the district court's determination that Transonic had established a likelihood of success on the issue of infringement was founded on an overly broad construction of the these terms, we vacate the preliminary injunction and remand for further proceedings consistent with this opinion.

Each party shall bear its own costs.

FOOTNOTES:

[1] The district court's opinion does not discuss the "calculating" and "determining" limitations of the claims. NMT does not argue that the Delta H method does not meet these limitations as they were construed by the district court. Rather, it contends that the court's claim construction was erroneous.